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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/443,072	11/18/1999	BRIAN A. ROSENFELD MD	483-001	6723

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EXAMINER

HARLE, JENNIFER I

ART UNIT

PAPER NUMBER

2167

DATE MAILED: 03/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/443,072

Applicant(s)

ROSENFELD MD ET AL.

Examiner

Jennifer I. Harle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-14 are pending. Claims 1-14 are rejected.

Specification

The disclosure is objected to because of the following informalities: pg. 7, line 1 "hose" should be "those"; pg. 16, line 15 "Detailed description of the Invention" should be "Detailed Description of the Invention". Application is requested to review the specification for other typographical errors and make the appropriate corrections.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 10-14 been renumbered 9-14 and where appropriate the dependency has been corrected, i.e. claim 12 now depends on claim 11 and claim 13 now depends on claim 12. Claim 14 remains dependent on claim 13. If applicant wishes to amend claim 14 depend upon claim 12. Appropriate correction is required.

Background

Applicants, Drs. Breslow and Rosenfeld formed a company, IC-USA (now VISICU), in either 1997 or 1998 for the deliver of critical care medicine based upon the disclosure set forth in this application. See e.g., Portfolio Case Studies IC-USA, <http://www.profilespr.com/pages/icusa.htm>, printed 1/31/02; Finding Value in Intensive

Care, From Afar, The New York Times, July 27, 1999,
http://www.visicu.com/companynews/0799_nytimes.htm, printed 01/31/02; Doctors use
'remote control' to monitor ICU patients, CNN.com. technology>computing, August 21,
2000, http://www.cnn.com/2000/TECH/computing/08/21/icut_t/; Cinda Becker,
Telemedicine System Helps Manage ICUS, Modern Healthcare, Vol. 30, Iss. 37,
September 4, 2000, pg. 62. The New York Times article states that the first client had
expressed in at least as early as July 27, 1999 and perhaps earlier that Sentana Health
Systems was interested in purchasing their services/system. Moreover the Becker article
discloses, Abell Foundation and California Cardinal Health Ventures participated in the
initial financing and would have been given some sort of business prospectus/disclosure
outlining the product and how it would work to entice their investment. It is unclear when
the first client was solicited and what information he received as well as when the first
solicitations for financing occurred and what business prospectus/disclosure was provided.
Applicant is requested to provide this information.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that
form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or
on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-14 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of
the invention.

Last in May 1997 a pilot study of applicant's system was conducted at Johns Hopkins University Hospital ICU. (See, e.g., Doctors use 'remote control' to monitor ICU patients, CNN.com. technology>computing, August 21, 2000, http://www.cnn.com/2000/TECH/computing/08/21/icu.t_t/; Finding Value in Intensive Care, From Afar, The New York Times on the Web, July 27, 1999, [www.Visicu.com/companynews/0799_nytimes.htm](http://www.visicu.com/companynews/0799_nytimes.htm); Telephone Conference with Karen Blum Assistant Director Media Relations Johns Hopkins, February 25, 2002) Intensivists, nurses and clinicians monitored over 10 ICU beds (plurality of health care locations) over long distances 24 hours a day from a remote command center (Remote Monitoring of ICU Patients Lowers Mortality Rates, Complications, Johns Hopkins Newsrelease, March 20, 2001, <http://www.newswise.com/articles/2001/3/ICU.JHM.html>). The intensivists used remote monitoring methodologies, video conferencing and computer-based data transmission, to obtain clinical information and to communicate with on-site personnel. (Brian A. Rosenfeld, M.D., FCCM, FCCP, et al., Intensive care unit telemedicine: Alternate paradigm for providing continuous intensivist care, Critical Care Medicine, Vol. 28, No. 12, 2000 pg. 3925). The intensivists interacted with the patients and staff, monitored data, including bedside monitors, electrocardiograms, radiographs, consultant notes, laboratory data, etc. (Id. at 3926). Inherent to these bedside monitors are warning systems, containing algorithms that prompt an intensivist to decide to provide care and treatment to a patient, i.e. a heart has stopped beating, breathing has stopped, gasses in the blood have become critical, loss of brain activity, etc. Thus, these algorithms would be used for

treating patients exhibiting symptoms associated with Brain Death, Congestive Heart Failure, Emergency Cardiac pacing, etc.

Through the use of this computerized data and computer based video transmission, the intensivists formulated a care plan (treated the patient) at the ICUs (Id.) and even wrote orders (Id.).

The Acute Physiology and Chronic Health Evaluation (APACHE) III computerized data from the first ICU day was compared with the national APACHE III database to determine the predicted risk of ICU and inhospital death and hospital length-of-stay for each patient (Id.). The data was also compared and included myocardial infarction, cardiac arrest, reintubation, pulmonary failure, acute renal failure, gastrointestinal bleeding, sepsis, and ICU readmission (Id.).

Thus, claims 1-14 are rejected over the pilot study as a prior public use.

Claim Rejections - 35 USC § 103

Claims 7-8, 10, 12-13 rejected under 35 U.S.C. 103(a) as obvious over the public use as set forth above and in view of Levin, et al. (5,724,580 or Benigno, et al. (6,230,142).

Assuming arguendo, that the algorithms are not inherent to the pilot study, both Levin (Summary of Invention) and Benigno (Summary of Invention) teach the use of clinical pathways using decision support algorithms to provide care for patients. Levin specifically teaches treating coronary diseases, therapeutic dosing, ischemia, lipids, cholesterol, and diabetes (See figures and Summary of Invention). Benigno teaches hypertension, diabetes, and vital signs (See figures and cols. 4-10). It would have been obvious to one of ordinary skill in the art at the time of the invention to include utilizing

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decision support algorithms in the applicant's invention as publicly disclosed to enhance and properly treat patients. It would have been obvious to verify the potential diagnosis and treatment utilizing a computerized clinical pathway and decision support algorithms as taught by Levin and Benigno to prevent inaccurate diagnosis and enhance reliability in the ICU environment. Thus, patient safety would be improved and liability would be decreased resulting in an overall benefit to everyone.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer I. Harle whose telephone number is 703.306.2906. The examiner can normally be reached on Monday through Thursday, 6:00 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P. Olszewski can be reached on 703.305.9643. The fax phone numbers for the organization where this application or proceeding is assigned are 703.308.5357 for regular communications and 703.308.5357 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.305.3900.

jih
February 25, 2002


Richard Chilcot
Supervising Patent Examiner
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2612